UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/DTS)
This Document Relates to All Actions	**PLAINTIFFS MOTION TO COMPEL DEFENDANTS' TO SUPPLEMENT DISCOVERY RESPONSES PURSUANT TO FRCP 26**

Pursuant to Rule 26(e), Plaintiffs bring this Motion to Compel supplemental productions to discovery served upon Defendants in 2016 and 2017.

Introduction

In connection with the general causation phase of this MDL, Plaintiffs propounded multiple sets of requests for production of documents and interrogatories beginning in June of 2016 and continuing through September of 2017.[1] Defendants responded to the various requests over the course of 2016, and last provided documents responsive to certain of Plaintiffs' requests on November 7, 2017.[2] Plaintiffs have reminded

[1] See Declaration of Genevieve M. Zimmerman. All Exhibits referenced in this memorandum are attached to the Declaration of Genevieve M. Zimmerman. Plaintiffs are cognizant of the Court's practice pointers directing that discovery requests be repasted in their entirety in connection with a motion to compel. However, because this motion to compel requests an order that discovery responses be supplemented broadly, and in light of the volume of requests served in this MDL, Plaintiffs are not restating each and every request in this Memorandum of Law. Should the Court prefer, Plaintiffs will gladly provide a complete copy of each discovery request served in this MDL.

[2] See Ex. 1 (11/7/17 email confirming receipt of Production 48).

Defendants of the obligations imposed by Federal Rule of Civil Procedure 26(e) to supplement discovery responses on multiple occasions,[3] but Defendants refuse to meet the obligations imposed upon them by the rules.[4]

Relevant Background

For the Court's benefit, Plaintiffs present the following information as a reminder about some of the key allegations involved in this MDL impacting over 5,000 people with cases pending before this Honorable Court.

A. The Bair Hugger: Environment of Use, Warnings, Risks, and Failure to Study

The Bair Hugger is a medical device used to warm patients. Originally cleared for marketing through the 510(k) process in the late 1980's, the predicate device for the Bair Hugger is the "Sweetland Bed Warmer & Cast Dryer", which dates to the late 1930's. The original Bair Hugger Model 200 was intended expressly for use outside the operating room, and that Model included a warning about airborne contamination. In the 1990s, the Bair Hugger Model 500 line was unveiled, which was intended for use inside the operating room. The warning about the risk of airborne contamination was removed from the Model 500 and Model 700 lines, and, unlike its modern day competitors such as the Stryker Mistral, the warning about the risk of airborne contamination has never been reintroduced to the Bair Hugger.

[3] See Ex. 2 (10/24/2018 Letter to Hulse); Ex. 3 (11/20/2018 Letter to Hulse); Ex. 4 (11/29/18 Letter to Hulse); Ex. 5 (11/30/2018 Letter to Hulse)

[4] See Ex. 6 (11/28/2018 Letter from Hulse acknowledging employees have created emails and documents that are responsive to previously served discovery requests, but refusing to supplement production because "general causation discovery is closed"); Ex. 7 (12/7/2018 Letter from Hulse)

Testimony at the *Gareis* trial confirmed Defendants assumed Bair Hugger provided a benefit to patients, and hoped there was no risk. At trial, 3M's former director of advanced technology, Gary Hansen, testified that the Bair Hugger's sole benefit is to maintain normothermia and that the company simply assumed the benefits of warming were the same for all surgeries. Tr. I at 70:13-70:32. Yet Defendants never studied the Bair Hugger to determine whether it was beneficial in orthopedic procedures. *Id.* at 71:16-21. Nor did the company conduct any risk-benefit analysis of Bair Hugger for this purpose. *Id.* at 92:13-25. Hansen unequivocally admitted that the Bair Hugger must be safe for its intended use. *Id.* at 88:19-22. He even admitted that if the Bair Hugger caused infection, it would be a risk, and the risk of the device would outweigh the benefits of its intended use. *See id.* at 106:14-106:23.

The case in a nutshell is about Defendants' assumptions about unproven benefits; the marketing of the Bair Hugger device for universal application despite a failure to study; and the known risks associated with promoting the universal use of medical equipment that is known to both harbor dangerous bacteria and to interfere with the airflow in an operating room designed to protect the patient at increased risk from particles that are capable of transmitting bacteria.

B. Critical Filter Changes Impact FDA Clearance and Patient Safety

Plaintiffs allege the filter currently in use on the Bair Hugger is inadequate to prevent the transmission of bacterial contamination. 3M's outside clinical consultant on normothermia, Dr. Daniel Sessler, testified regarding filtration, noting the importance of

whether "forced air warmers pick up bacteria" or "retain bacteria."[5] According to Dr. Sessler, "[i]f they do, that's a problem."[6] The early Bair Hugger Model 500 series units filtered approximately 95% of .2 micron particles. That filter was the basis for the safety claims in the Bair Hugger's federal clearance. In the "Summary of Safety and Effectiveness" for the Bair Hugger Model 505, the company assured the government that its filter would safeguard against "airborne contamination," and it cited [redacted]"[7]

However, the modern Bair Hugger Model 750 was cleared to market based on the false assurance to the FDA that it would include "a filter equivalent to the [Model] 505 filter."[8] The Defendant's Director of Research & Development testified that in truth, the Model 750 [redacted]

[5] Deposition of Dr. Daniel Sessler, at 64:21, attached as Exhibit 8.
[6] *Id*. at 64:23.
[7] 3MBH00047382, attached as Exhibit 9.
[8] 3MBH01897094, attached as Exhibit 10.
[9] Deposition of Gary Hansen, at 30:15, attached as Exhibit 11.
[10] 3MBH00022367, attached as Exhibit 12.

In a 2003 email, the Defendant's Regulatory Compliance Manager and its Director of Research and Development cautioned [redacted]"[14] A letter-to-file must be created to ensure that a company has performed a safety validation on a design change. In this case, [redacted][15]

During a FDA facility inspection in 2009, [redacted]

[11] 3MBH01031246, attached as Exhibit 13.
[12] Id.
[13] Id.
[14] Id.
[15] 3MBH00018311, attached at Exhibit 14.
[16] 3MBH00048067, attached at Exhibit 15.

[redacted]

In 2013, the company's Clinical Director admitted in an internal memo [redacted]"[23]

C. The Undisclosed Filter Change Leads to Bacterial Contamination

In the years following the filter efficiency reduction on the Bair Hugger, the company began to receive reports from a variety of sources -- who had nothing to do with

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[17] Id.
[18] Id.
[19] 3MBH00107862, attached as Exhibit 16.
[20] 3MBH00126140, attached as Exhibit 17.
[21] 3MBH00132832, attached as Exhibit 18.
[22] 3MBH00008025, attached as Exhibit 19.
[23] Ex. 8 (Deposition of Daniel Sessler, at 34:21).

Dr. Augustine -- that Bair Huggers were harboring and incubating dangerous bacteria beyond the filter. For example, in a 2004 report published in Infection Control and Hospital Epidemiology entitled *Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment*, the authors reviewed medical equipment in operating rooms involved in an outbreak of dangerous infections.[24] The authors concluded "contaminated dust" from the interior of a Bair Hugger harbored a strain of A. baumannii bacteria responsible for the outbreak.[25] When the contaminated unit was removed, the outbreak stopped. In the same year, the company's Clinical Director acknowledged to company executives in an internal email [redacted]

[redacted]

[redacted]„[26]

After other similar reports, the company sent a letter in 2006 to certain customers who made inquiries on the subject of internal contamination. The letter acknowledged that bacteria had been cultured from Bair Huggers but sought to assure customers there was no risk if "the Bair Hugger system is used and maintained properly."[27] Yet in 2008, the company's Clinical Director warned management [redacted] The Clinical Director repeated that warning the following year, noting [redacted]

[redacted]

[redacted] This warning was never passed on to customers.

Another example arose later that same year when the company became aware of a situation similar to that described in the 2004 Infection Control journal. The company learned [redacted][30] Also in 2009, the company became aware of research performed by five physicians at Stanford University concerning internal contamination. The researchers at Stanford discovered twelve of twenty-nine Bair Huggers tested had bacterial growth in the distal ends of the machine, beyond the filter.[31] Unaware of the reduced filtration, the Stanford researchers speculated the problem might be related to the filter change interval.[32] The Stanford researchers also noted the recommendation to add a HEPA filter to the distal end of the Bair Hugger hose.[33] [redacted].

D. [redacted]

[redacted]

[29] 3MBH00002647, attached as Exhibit 24.
[30] 3MBH00024633, attached as Exhibit 25.
[31] 3MBH00024678, attached as Exhibit 26.
[32] *Id.*
[33] *Id.*
[34] 3MBH00545125, attached as Exhibit 27.

[redacted] However, 3M does admit as few as one or two bacterial colony-forming units or "CFU's" can cause an infection in orthopedic surgery.

[redacted]

[35] 3MBH00022625, attached as Exhibit 28.
[36] Id.
[37] Id.
[38] 3MBH00022877, attached as Exhibit 29.
[39] Id.
[40] Id.

[redacted][41]

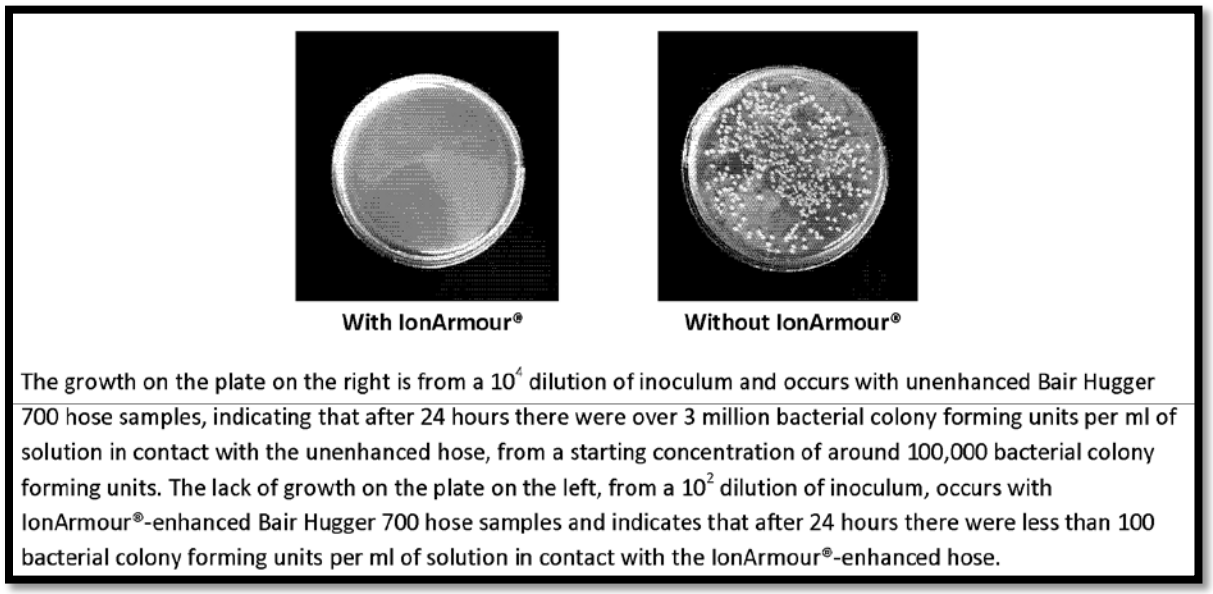
[redacted].

[redacted]

[redacted] In a customer letter regarding internal contamination sent prior to Project Ducky, Defendant told its customers "none of the materials used in the warming hose, however, support the growth of any known bacteria."[42] [redacted]

[41] 3MBH00022625, at Ex.28.
[42] 3MBH00008941, at Ex.22.

[redacted] [45]



[46]

[redacted]

[43] 3MBH00031184, attached as Exhibit 30.
[44] Id.
[45] Id.
[46] Id.
[47] 3MBH00022625, Ex.28.
[48] Deposition of Teri Woodwick-Sides, 139:18, attached at Exhibit 31.

[redacted]

E. Growing awareness of adverse scientific data

Internal talking points created for the company's sales teams in 2010 [redacted] "[51] Yet, the company was already aware of numerous peer-reviewed scientific studies which found evidence of Bair Huggers interfering with operating room airflow and creating a contamination risk. [redacted]

[49] 3MBH00022625, at Ex. 28.
[50] Id.
[51] 3MBH00005575, attached as Exhibit 32.
[52] 3MBH00052987, attached as Exhibit 33.
[53] Id.

[redacted][55]

Over the next few years, Defendants began to realize the scope of the problem in the face of growing evidence. [redacted]„[57]

Numerous scientists and surgeons recognized the risk of forced-air warming well before any litigation by patients. Indeed, prior to the first Bair Hugger lawsuit, McGovern, et al., "found a significant increase in deep joint infection, as demonstrated by an elevated odds ratio (3.8, p = 0.024), [during] a period when forced-air warming was used compared to a period when conductive fabric warming was used." McGovern, P., et al. *Forced-air warming and ultra-clean ventilation do not mix*. J Bone and Joint Surg-Br. 2011;93(11):1537–44.

[54] 3MBH00053468, attached as Exhibit 34.
[55] Id.
[56] 3MBH00109033, attached as Exhibit 35.
[57] 3MBH00580475, attached as Exhibit 36.

3M's attempts to discredit this study, along with numerous other studies cited in Plaintiffs' Master Complaint, have failed. All the depositions of study authors both confirmed and added to its alarming results. For example, Dr. McGovern repeatedly explained during his deposition "there was a 3.8 times more likely rate that a patient would incur a deep joint infection with the use of a forced-air warming device than with a conductive fabric warming device."[58] Co-authors Dr. Michael Reed and Professor Christopher Nachtsheim also gave testimony confirming the nature and importance of the study's findings. Dr. Reed highlighted the 3.8 risk ratio,[59] while Professor Nachtsheim discussed additional data demonstrating the change in antibiotic and thromboprophylaxis regimens did not confound the 3.8 odds risk ratio.[60] Dr. McGovern further explained the data collected post-publication continued to show that forced-air warming was associated with "a three times or more higher incidence of infection" compared to air-free warming.[61] Dr. McGovern also testified -- contrary to 3M's repeated yet baseless refrain -- that he "did not receive any compensation from Augustine … with respect to conducting the study."[62]

F. Manufacture and manipulation of dubious research to deny Bair Hugger risk

In an attempt to respond to the growing concern over the Bair Hugger's ability to contaminate operating room airflow, [redacted]

[58] Deposition of Dr. Paul McGovern, at 372:9-14, attached as Exhibit 37.
[59] Deposition of Mr. Michael Reed, at 219:12-18, attached as Exhibit 38.
[60] Deposition of Christopher Nachtsheim, at 328:14-348:2, attached as Exhibit 39.
[61] Depo of Dr. Paul McGovern, at 415:8-20, at Ex. 37.
[62] Id., at 356:9.

[redacted]

[63] 3MBH00001557, attached as Exhibit 40.
[64] 3MBH00050756 , attached as Exhibit 41.
[65] Deposition of Daniel Sessler, p. 41:16-19, Ex. 8. Importantly, given 3M's attempt to negate the import of particles as a reliable proxy for bacteria during the course of this litigation, it is worth noting the Sessler/Olmstead study was entirely ***focused on particles as a proxy for bacteria, and thereby the risk of infection***.
[66] Id., p. 66, at Ex. 8.
[67] Id., p. 68.

[redacted][68]

[redacted]

[redacted]

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68 3MBH00024809, attached as Exhibit 42.
69 3MBH01224622, attached as Exhibit 43.
70 3MBH00130429, attached as Exhibit 44.
71 Id.
72 Id.

[redacted]

[73] Id.
[74] Id.
[75] 3MBH00083780, attached as Exhibit 45.
[76] Id.
[77] 3MBH01211442, attached as Exhibit 46.
[78] Id.

[redacted]

[redacted] Despite its willingness to create what was essentially a commercial advertisement for the product under the guise of independent research, the company steadfastly refused to perform any serious testing on the issue of bacterial infections.

G. Attempts to avoid a genuine contamination study

[redacted]

In November of 2011, [redacted]

[redacted]

[79] 3MBH00051252, attached as Exhibit 47.
[80] 3MBH00575107, attached as Exhibit 48.
[81] 3MBH00575251, attached as Exhibit 49.
[82] Id.
[83] 3MBH00132501, at Ex.50.

[redacted]

In January 2012, [redacted]

[84] Id.
[85] 3MBH01619270, attached as Exhibit 51.
[86] Id.
[87] Upon information and belief, Dr. Parvizi is both a member of 3Ms Advisory Board and the Editor in Chief of the ICOS consensus document.
[88] 3MBH00555876, attached as Exhibit 52.
[89] 3MBH00130429, at Ex.44.
[90] Id.
[91] Id.
[92] Id.

[redacted]

[redacted].”[95]

In March 2013, Dr. Sessler and Defendants’ Director of Research and Development discussed the increasing volume of literature regarding an infection risk from the Bair Hugger. [redacted]

[redacted][99]

H. 3M’s claim of medical benefits from using the Bair Hugger in orthopedic surgeries is not supported by any scientific evidence

3M promoted the Bair Hugger forced air warming system to orthopedic surgeons. In so doing, 3M claimed the Bair Hugger maintains normothermia and that maintaining normothermia reduces the incidence of infection and length of hospital stay. Depositions

[93] Id.
[94] Id.
[95] Id.
[96] 3MBH00134035, attached as Exhibit 53.
[97] Id.
[98] 3MBH00107719, attached as Exhibit 54.
[99] Id.

in this case have confirmed these claims have no scientific support. Dr. Andrea Kurz[100], a paid member of 3M's Scientific Advisory Board and an author whose publications 3M claims supports the alleged health benefits of Bair Hugger, agreed that "[i]n today's scientific standards, there is no reliable evidence that supports that maintaining normothermia reduces the incidence of infection"(emphasis added).[101] Although Dr. Kurz informed 3M that there is no evidence that maintaining normothermia (using the Bair Hugger) reduces the incidence of infection in orthopedic surgery,[102] 3M has continued to falsely promote and market the Bair Hugger in orthopedic surgeries without any scientific evidence the product reduces the incidence of periprosthetic joint infections.[103]

Ironically, current studies indicate there is no statistical difference in wound infections between patients who are warmed perioperatively and those who are not.[104] Dr. Daniel Sessler, another paid 3M Scientific Advisory Board member, also testified that the mid-1990 studies that 3M relies upon are beginning to be discredited and would not meet scientific scrutiny in order to be published today.[105] 3M is ignoring the current science and relying on bad science, all the while falsely claiming the Bair Hugger system reduces the length of stay for patients in the hospital. Dr. Kurz also testified that there is no

[100] Dr. Kurz is a leader in the research of normothermia and has written many articles that 3M relies upon to promote the Bair Hugger warming system.
[101] Deposition of Andrea Kurz, at 179:16, attached as Exhibit 55.
[102] Id. at 119:7, 13-19.
[103] Id. at 179:4 to 179:6)
[104] Id. at 171:8; see also Scott AV, Stonemetz JL, Wasey JO, Johnson DJ, Rivers RJ, Koch CG, Frank SM. *Compliance with Surgical Care Improvement Project for Body Temperature Management (SCIP Inf-10) Is Associated with Improved Clinical Outcomes*. Anesthesiology. 2015;123:116–25
[105] Depo. of Daniel Sessler, at 118:21, at Ex. 8.

reliable evidence that maintaining normothermia during the intraoperative period reduces the length of stay for patients.[106]

Blowing hot air in the operating room negates any positive effect of HEPA air coming downward over the sterile operative site during an ultra-clean surgery. 3M has no credible scientific evidence to support its claims that the use of the Bair Hugger (placing a blower below the operating room table) reduces the incidence of wound infections or length of stay for patients.

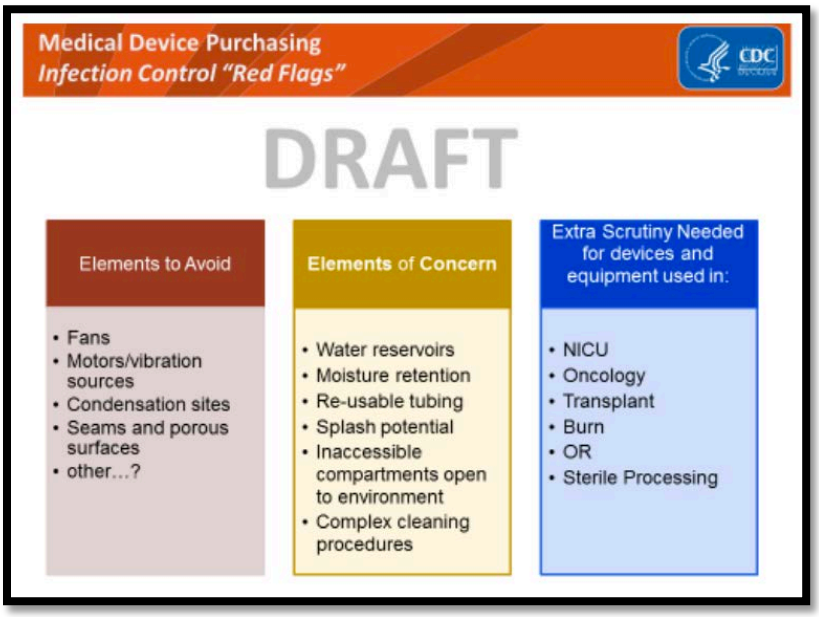
I. There are multiple safer ways to keep a patient warm

Plaintiffs also allege safer design alternatives to the Bair Hugger exist.[107] One such alternative is conductive warming blankets or mattresses such as theVitaHEAT resistive heat mattress. The VitaHEAT UB3 product is a conductive warming mattress designed to be placed under a patient, allowing the clinician to adjust the temperature.[108] The makers of VitaHEAT note "[t]here is no forced air to warm up clinicians tending the patients."[109] And VitaHEAT touts "CONDUCTIVE HEAT warms the patients without circulating air."[110] Dr. Daniel Sessler, a clinical consultant retained by 3M, has concluded resistive heat mattresses are equally effective to the Bair Hugger in maintaining temperature in patients undergoing surgery and has published studies confirming the same.[111] Those

[106] Depo. of Andrea Kurz, at 87:22, at Ex. 55.
[107] See Plaintiffs' Master Long Form Complaint at Paragraph 95.
[108] Exhibit 56, Vitaheat Product Information.
[109] Id.
[110] Id.
[111] Depo. of Daniel Sessler, at 125:2, at Ex. 8.

studies concluded "core temperatures were no different, and significantly noninferior, with underbody resistive heating than upper-body forced-air warming."[112]

In late 2015, the U.S. Centers for Disease Control recently concluded equipment capable of circulating air should not be used in operating rooms. In 2015, the Healthcare Infection Control Practices Advisory Committee ("HICPAC) of the CDC stated that "[n]othing that blows air should be in an operating theater, if possible."[113] Furthermore, in 2016, HICPAC continued to discuss this issue and stated "[a]ir current generation: devices that blow air should probably not be situated in high-risk locations"[114] HICPAC also prepared the below chart to guide medical device purchasers with respect to equipment to be used with patients:[115]



[112] Depo. of Daniel Sessler, at 125:2, at Ex. 8.
[113] Exhibit 57, DRAFT CDC HICPAC Meeting Minutes, November 5-6, 2015, p. 27
[114] Id., at p. 29.
[115] Id.

In light of the foregoing, it is now clear there is no scientific justification for the use of the Bair Hugger in orthopedic surgeries, especially given the demonstrated hazards of these products, the established high risk nature of any surgery involving implantable prosthetic devices, and the availability of alternative devices.

J. Developments since the Close of General Causation Discovery

Counsel for Defendants admitted during the three day *Daubert* hearing that the infamous August 2017 FDA letter came about at 3Ms request.[116] Some of the documents evidencing Defendants' successful effort to lobby the FDA to obtain that letter were produced after the three day *Daubert* hearing. The documents produced on November 17, 2017 confirm 3M's lobbying efforts stretched back for, at a minimum, nearly a year. Despite the fact that these documents were admittedly responsive, Defendants failed to produce them in a timely manner – not until well after the close of both general causation discovery and expert discovery on general causation issues. As a result, Plaintiffs were denied the opportunity to conduct discovery into the nature and extent of 3M's lobbying efforts, or to uncover the limitations on information provided by 3M to the FDA in connection with the lobbying efforts. Several months later, in April, 2018 in preparation for the *Gareis* trial, still more admittedly responsive, yet never previously produced documents were provided to Plaintiffs in connection with pretrial disclosure requirements for exhibits.

In addition, over the past year the *International Consensus on Prevention of Periprosthetic Joint Infection* met for the second time in July, 2018. 3M was a

[116] Trans. Oct 24, 2018 (20:24-21:25)

"Platinum" sponsor of the event, and none other than the orthopedic expert identified by Defendants in this MDL and called to trial in *Gareis* – Dr. Michael Mont – was one of only four named outside editors who reviewed the entire 2018 edition of the ICOS.[117] Even before this litigation, the ICOS had long been recognized by 3M as a reliable and authoritative. Defendant reiterated during the *Daubert* hearings the importance of the ICOS. In 2018, the ICOS published the second ever consensus statement. Despite 3M's involvement as a sponsor, as well as through their identified expert in orthopedics in this very MDL, no documents related to the 2018 ICOS have been produced as a supplement to previous productions.

Finally, 3M is a sponsor of the "RIIiO" study,[118] whose principal investigator is Mr. Michael Reed.[119] Mr. Reed is, of course, also the principal investigator and named author in the McGovern study, and was deposed during this MDL. The pilot RIIiO study has been underway since 2016, with expected results available any day.[120] Despite the fact that this pilot study is funded by Defendants, and conducted by one of the key researchers deposed in this case, Defendants refuse to produce any documents reflecting or relating to this study. This is particularly troubling because, upon information and

[117] See https://icmphilly.com/ (last visited December 27, 2018).

[118] Ex. 58 (Michelle Kumin, Christopher Mark Harper, Mike Reed, Stephen Bremner, Nicky Perry and Matthew Scarborough, *Reducing Implant Infection in Orthopedics ("RIIiO"): a pilot study for a randomized controlled trial comparing the influence of forced air versus resistive fabric warming technologies on postoperative infection rates following orthopaedic surgery in adults*, TRIALS (2018) (available at https://trialsjournal.biomedcentral.com/track/pdf/10.1186/s13063-018-3011-y)(last visited December 27, 2018)). Upon information and belief, Mr. Harper is also a member of 3M's Scientific Advisory Board. His deposition was scheduled to take place in September, 2016, but, as the record reflects, was cancelled by Defendants "for strategic reasons".

[119] Id.

[120] Id.

belief, 3M declined to continue funding the remainder of this randomly controlled clinical trial which has a specific aim to "investigate whether the risk of post-operative orthopedic implant infection is influenced by the choice of intraoperative warming technology."[121] The question Reed et. al are attempting to answer with the RIIiO study goes to the very heart of the dispute in this MDL. Yet Defendants reportedly declined to continue to fund the research efforts, and refuse to supplement discovery responses here. Defendants' suggestion that there is no obligation under FRCP 26(e) to supplement discovery until/unless a previous response is incomplete or incorrect "in some *material* respect"[122] cannot be made in good faith. Accordingly, Plaintiffs respectfully move this Court for an order compelling a complete supplemental production.

Argument

Discovery is intended to "discover" facts and evidence germane to the lawsuit, and hence parties are authorized-indeed obligated-to supplement their disclosures regarding relevant facts, witnesses, etc. See *Schwing v. Putzmeister*, 168 F. Supp. 2d 1023, 1025 (D. Minn. 2001) *aff'd in part, vac'd in part*, 305 F.3d 1318 (Fed. Cir. 2002)*;ADC Telecomms., Inc. v. Thomas & Betts Corp.*, 2001 WL 1381098 (D. Minn. October 18, 2001). The purpose of Rule 26(e) is to preclude "trial by ambush." *Transclean Corp. v. Bridgewood Servs., Inc.*, 101 F. Supp. 2d 788, 797 (D. Minn. 2000). The "bedrock consideration" is that unfair surprise should be prevented. *See Transclean Corp. v. Bridgewood Servs., Inc.*, 77 F. Supp. 2d 1045, 1063 (D. Minn. 1999).

[121] Id.
[122] Ex.6 (Hulse letter 11/28/18).

Under Rule 26(e), "[a] party who has made a disclosure under Rule 26(a) - or who has responded to an interrogatory, request for production, or request for admission - must supplement or correct its disclosure or response" in a timely manner upon learning that the initial disclosure or response is incomplete or incorrect in some respect. Fed. R. Civ. P. 26(e). The Rule specifically refers to "additional" information. The comments to the Rule refer to *supplementations* "as each *new item of information* is learned"." *See* Fed. R. Civ. P. 26, Adv. Comm. Notes 1993 Amendment, Subd. (e) (emphasis added). The Rules have only one test for whether supplementation is required: whether the "disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). "Excluding documents created after the close of discovery from the duty to supplement would encourage parties to wait until after discovery has closed to create documents containing potentially damaging information." *Iweala v. Operational Techs. Servs., Inc.*, 2010 WL 11583114, at *2 (D.D.C. Apr. 13, 2010); *see also Pizza Pub. Co., Ltd. v. Tricon Glob. Restaurants, Inc.*, 2000 WL 1457010, at *1 (S.D.N.Y. Sept. 29, 2000). Defendants therefore have an obligation to supplement discovery responses. To date, however, Defendants have refused to produce a single responsive document in over a year, and have failed to supplement its prior Interrogatory and/or other discovery responses.[123]

[123] A "Court may also impose a number of other sanctions for failure to comply with the Rule 26(e) duty to supplement or correct a discovery response 'on motion and after giving opportunity to be heard.'" *Pny Tech. Inc. v. Polaroid Corp.*, 16-cv-01357 JRT, 15-16 (D. Minn. March 29, 2017)(quoting Fed. R. Civ. P. 37(c)(1)). Because Defendants have refused to provide any

Allowing Defendants to escape the mandatory duty to supplement discovery responses is fundamentally at odds with the purpose of discovery in civil litigation; Defendants in this litigation and beyond would interpret such an order as permission to avoid producing relevant, responsive documents in the hopes the nondisclosure isn't discovered before the close of discovery, after which point a motion to compel would be presumptively denied as untimely. But this is not and cannot be the way discovery works. Defendants continue to market the Bair Hugger as safe for use in orthopedic implant surgeries. Defendants surely have a host of documents, communications, website, blog, and YouTube posts fraudulently extolling the supposed benefits associated with use of Bair Hugger without any mention of the corporate concession that the Bair Hugger hosts and harbors bacteria, or the knowledge about the risk of airborne contamination and the near universe concern about the importance of reducing particles over the sterile field in orthopedic surgery. These items are surely responsive to discovery requests propounded in this litigation, and should be supplemented pursuant to the Federal Rules.

Conclusion

For all of the reasons stated above, Plaintiffs respectfully request that the Court enter an Order compelling Defendants to immediately and completely supplement the

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substantive discovery responses or timely supplement to prior discovery responses, and has not produced a single document responsive to Plaintiffs' requests, the Court should order, pursuant to Rule 37, that Defendants immediately provide the requested information. *See* Fed. R. Civ. P. 37. Further, because Plaintiffs have attempted, in good faith, to solicit Defendants' cooperation without the intervention of the Court, Defendants should be ordered to pay Plaintiffs' reasonable expenses incurred in making this motion. Fed. R. Civ. P. 37(a)(5).

discovery responses as required by Rule 26(e), and order Defendants to pay Plaintiffs expenses incurred in bringing this motion.

Dated: December 28, 2018

Respectfully submitted,

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